DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 5, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Cathy Groupe, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: *groupec@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the Information line for up-to-date information on this meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) S–036 to approved new drug application (NDA) 19–787, NORVASC

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(amlodipine besylate) Tablets (2.5 milligrams (mg), 5 mg, and 10 mg), Pfizer Inc., proposing a change in labeling for the following two additional indications of: (1) Reducing the risk of fatal coronary heart disease and nonfatal myocardial infarction and (2) reducing the risk of stroke, based on the effectiveness demonstrated in the antihypertensive and lipid lowering treatment to prevent heart attack trial (ALLHAT).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 29, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 29, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact John Lauttman at 301–827–7001 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 3.2.05
March 2, 2005.

Sheila Dearybury Walcoff,
Associate Commissioner for External Relations.

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